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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,707	06/07/2001	Theresa M. Allen	5325-0148.34	1073

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/876,707

Applicant(s)

Allen

Examiner  
Gollamudi S. Kishore, Ph.D

Art Unit  
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 28, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-32 and 57-81 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-32 and 57-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

**The requests for the extension of time and reconsideration dated 1-28-02 are acknowledged.**

**Claims included in the prosecution thus, are 21-32 and 57-81.**

#### ***Claim Rejections - 35 U.S.C. § 102***

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

**A person shall be entitled to a patent unless --**

**(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.**

**(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

- 2. Claims 21-25, 60 and 71 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Torchilin (5,534,241).**

**Torchilin discloses a polymer system (DTPA-polylysine) one end of which is attached to a lipid and the other to either a therapeutic or diagnostic polychelator (targeting ligand); (note the abstract, figures, columns 4-5, 9-13 and claims).**

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**Note: the 102 (b) rejection would be reconsidered upon the determination of the contents of the provisional application. Applicant's help in this regard is requested.**

**Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Torchilin does not teach the targeting ligand. This argument is not found to be persuasive. Claims are interpreted in their broadest sense and the reference's chelating moieties are targeting ligands since on col. 8, line 64 et seq., Torchilin states that these are accumulated in liver, spleen, lymph nodes and bone marrow and that other organs can be imaged using antibody mediated targeting. This statement implies that without antibodies the complexes accumulate in liver and other organs and therefore, they are targeting ligands.**

***Claim Rejections - 35 U.S.C. § 103***

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

**(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.**

- 4. Claims 21-32 and 57-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torchilin cited above, further in view of Harris (5,932,462).**

**The teachings of Torchilin have been discussed above. Although Torchilin teaches the use of other targeting groups such as enzymes, lectins and antibodies in the liposomes**

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compositions, Torchilin does not specifically teach that these ligands could be attached to the polymer instead of the polychelating ions.

Harris while disclosing a multi-armed polymer systems containing PEG-lysine polymers teaches that the polymer functional groups could be activated to couple to various target ligands (columns 12, 26, 36, 37 and claims).

It would have been obvious to one of ordinary skill in the art to use any targeting molecule in the polymer complex of Torchilin with the expectation of obtaining at least similar results since Harris teaches that any ligand could be coupled to the hydrophilic polymer system.

Applicant's arguments with regard to Torchilin have been addressed above.

Applicant argues that Harris is limited to a protein -polymer conjugate or a lipid-polymer conjugate or a ligand-polymer conjugate and not lipid-polymer-ligand conjugate. The examiner agrees and points out that if Harris had taught lipid-polymer-ligand conjugate, then the reference would have been a 102 reference. Applicants argue that they fail to understand how the combined teachings in the cited arguments arrive at the claimed invention. The examiner presents the following rationale. First of all, in response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the

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knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, although Harris is directed to a polymer ligand combination, on col. 2, line 45 through col. 3. Line 20 the reference clearly teaches that polyethylene glycol (same as in instant invention) has two functional hydroxyl groups and both could be activated to react with amino groups and Harris is clearly indicative of the attachment of targeting ligands to one of the activated groups. The primary reference of Torchilin as discussed above and as recognized by applicants themselves, teaches the attachment of polyethylene glycol to the liposome surface via amino linkages on the phospholipid headgroup (note also col. 10, lines 15-55) and Torchilin also provides guidance to attach one end of the polymer chain to the liposomal surface and the other to the chelating ligand. It is therefore, would have been obvious to one of ordinary skill in the art from the combined teachings of Torchilin and Harris to couple a targeting ligand and the liposomal surface to PEG with a reasonable expectation of success. The rejection is maintained.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

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more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

*gsk*

April 16, 2002